REMARKS

The amendments to the claims do not add new matter. Claim 59 was amended, consistent with the preambular term "elongated," to recite "said first side wall and said second side wall being elongated relative to said anterior end and said posterior end." Support for this recitation is found in various parts of the specification, including Figures 8D through 8G and the discussion of these Figures in the specification at page 17, line 27 to page 9, line 2. Claims 60 and 61 were amended to use the term of art "comprises." Claim 65 was amended to correct a typographical error in the phrase "wherein said substantially planar upper surface, ~~and~~ said substantially planar lower surface, or both." The prior use of "and" instead would preclude the need for the recitation of "or both" in the claim. Support for having ridges on the upper surface, or the lower surface, or both is found throughout the specification, including at page 3, lines 3-4 ("FIG. 5 provides a view of an apparatus for inscribing retention teeth in the upper surface, lower surface or both upper and lower surfaces of the implant.") and at original claim 51. Claim 69 was amended to correct dependency from pending claim 59 rather than cancelled claim 1. Claim 70 was amended to be consistent with the recitation in claim 59 regarding the structure of the implant, *i.e.*, "said first side wall and said second side wall being elongated relative to said anterior end and said posterior end."

New claims 72-79 parallel original claims 59-66 with the exception that claim 72 includes the recitation of an additional structural feature that **further** distinguishes it from the cited prior art. Specifically, claim 72 is directed to an elongated implant that is characterized by being "free of a through hole comprising the intramedullary canal of the source bone and extending between said upper surface and said lower surface." Support for this recitation is found in FIGS. 8D through 8G, depicting a slender, elongated implant, and the discussion thereof. Claims 73 parallels claim 60. Claims 74-77 parallel claim 61 but add further dependencies to members of the group and further add the more restrictive term of art "consists of" in lieu of the open term "comprises". Claims 78 and 79 parallel claims 65 and 66. In addition, claim 80 parallels claim 79, except that it recites dependence from dependent claim 77 rather than independent claim 72. For all these reasons, the amendments to the claims do not add new matter.

Bases for Rejection

Claim 69 is rejected under 35 U.S.C. § 112(second paragraph) for allegedly being indefinite for depending from a cancelled claim.

Claims 59-61, 65-66 and 70-71 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,728,159 (Stroever).

Claims 59-61, 65-66 and 70-71 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,371,988 (Pafford).

Claims 59-61, 65-66 and 70-71 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 6,371,988 (Pafford) in view of U.S. Pat. 4,349,921 (Kuntz).

The Applicants will address each basis for rejection in Sections I-IV, respectively, which follow.

I. 35 U.S.C. § 112, Second Paragraph

Claim 69 is rejected under 35 U.S.C. § 112(second paragraph) for allegedly being indefinite for depending from a cancelled claim. The Applicants have amended claim 69 to recite dependency from claim 59. Accordingly, this basis for rejection has been rendered moot.

II. Anticipation over U.S. Pat. 5,728,159 (Stroever)

(Claims 59-61, 65-66 and 70-71)

Claims 59-61, 65-66 and 70-71 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,728,159 (Stroever). Claim 59 and its dependents are directed to "[a]n elongated bone implant . . . ." The dictionary definition of the term "elongated" means "long in proportion to width:Slender. [Exhibit D of the Second Response to the Official Action of 09/29/03: Webster's' Ninth New Collegiate Dictionary, Merriam-Webster Publishers, Springfield MA, 1988 at page 404.] According to the Patent Office, "the term 'elongate' used in the preamble . . .fails to breath life and meaning into the body of the claim and is given no patentable weight." [Official Action at page 3.] The Applicants respectfully disagree because the term "elongate" is a structural term and is not

merely a statement of purpose as is the remaining recitation ("for use in spinal fusions") in the preamble. However, to eliminate this argument, the Applicants have amended the body of claim 59 to now recite, "said first side wall and said second side wall being elongated relative to said anterior end and said posterior end." Accordingly, the body of claim 59 now has a structural recitation that goes along with the preambular term "elongated."

In its anticipation argument, the Patent Office states that the implant of FIG. 2 of Stroever "has four side walls." This is factually incorrect. Stroever, like the Applicants, teaches that the implant has a "sidewall 14". {Stroever at col. 2, lines 1-2 ("the body portion 12 having a sidewall portion 14.") The assertion that the implant of Stroever has "four side walls" is also a misstatement of the convention in the medical art wherein the faces of the implant are designated in relation to the orientation in the human body. In medical parlance, the human body has two sides, a right side and a left side (or a medial-lateral orientation), and an anterior (front) face and a posterior (rear) face. Stroever, which is relied upon by the Patent Office, teaches this same orientation in relation to its implant. Specifically, Stroever, teaches that the "A" and "P" of the implant of FIG. 2 (and all other figures) are the "anterior/posterior (A/P) direction" and the "M" and "L" faces are the "medial/lateral direction." [Stroever at col.2, lines 7-11 ("In preferred embodiments, at least about three grooves 18 are cut parallel in end faces 16 in the **anterior/posterior (A/P)** direction of section 10, and at least about three grooves 20 are cut parallel in end faces 16 in the **medial/lateral (M/L) direction** of section 10."); emphasis added in bold.] Thus, in the medical art, the A and P faces of Stroever are not "side walls" and Stroever cannot have 4 side walls as argued by the Patent Office. In addition, Kuntz, which is cited by the Patent Office on the issue of obviousness, discloses that as of its issue date (09/21/82) that those skilled in the art were referring to implants as having "**opposed anterior and posterior ends.**" [Kuntz at col. 2, lines 61-68 ("According to one aspect of the invention there is provided an intervertebral disc prosthesis, comprising a body of biologically compatible material having a superior surface, an inferior surface and **opposed anterior and posterior ends**, and means located at one of said opposed ends for facilitating holding of the prosthesis during its insertion into or removal from an intervertebral disc space."); emphasis added in bold.] By analogy, when the surgeon enters the patient from the "anterior" face, one skilled in the art recognizes that he is not entering

from the "side." Likewise, the implant that the surgeon inserts between the vertebrae of the patient has its "anterior" and "posterior" ends orientated with the anterior and posterior faces (ends) of the patient. The surgeon does not put it in sideways and say "a side is a side". By further analogy, if you are driving your car and get hit in the "side," you did not get hit in the "front" or the "rear". Thus, the Applicants' specification, which is in the medical arts, must be construed using the conventional medical terminology as employed by the Applicants and by the cited art (Stroever and Kuntz).

The Patent Office also argues in relation to the implant of FIG. 2 of Stroever that "[o]n the other hand, giving weight to the term 'elongate' the implant is 'stretched out' **between** the L and M **side walls** and therefor is an 'elongate bone implant.'" [Official Action at page 3; emphasis added in bold.] "L" and "M" are not sidewall but refer to the medial –lateral directions. [Stroever at col. 2, line 10.] However, if the implant of FIG. 2 is "stretched out between the L and M side walls" then the L and M side walls would not be longer than posterior "P" end. Rather, the posterior end of the implant of FIG. 2 would be elongated[1] relative to the L and M side walls. In contrast, Applicants' claim 59 has been amended to recite that the side walls are elongated relative to both the **anterior end** and the **posterior end** (*i.e.*, "said first side wall and said second side wall being elongated relative to said anterior end and said posterior end."). Separately, the implants of Stroever have lengths in the A/P direction and widths in the M/L direction that are substantially equal. This is evident because Stroever refers to the shaped implants of FIGS. 1-5 as having a "diameter." [Stroever at col. 2, lines 21, 34, 47, and 66.] Hence, they are not elongated implants in any sense of the word. Moreover, the implants of FIGS. 6 and 7 of Stroever are referenced in terms of "width". Width is not length. Pinocchio had a long nose, not a wide nose. Thus, none of the implants of Stroever are "elongated" as that term is used in its conventional sense or as Applicants' claims now recite.

[1] The term "elongate" is used in the Patent Office's sense in this sentence only. In the world and in the art, something is "long" or "elongate" as determined from the front to the back position. The Patent Office' reference to the implant of FIG. 2 being stretched out between the L and M side walls (*i.e.*, in the sideways direction) means that in common everyday words that the implant is "wide" rather than "long" or elongate.

For all these reasons, Stroever is not anticipatory of claim 59 or any of its dependent claims (claims 61-62 and 65-69) or any of the method claims (claims 70-71) that recite the same implant structure as recited in claim 59.

(Claims 72-80)

New claims 72-80 would not be anticipated for the reasons described above and for an additional reason. The implants of Stroever are "cross-sections" of tibia, humerus or femur. (Stroever at FIGS 8A-8C, and at col. 2, line 20 ("fibular cross-section bone grafts")]. As such, each of the cross-sectional implants of FIGS. 1-7 shows the naturally occurring medullary (aka "intramedullary") canal as a through-hole which runs from the top surface to the bottom surface of the resulting implants. Moreover, Stroever expressly states that each of his implants is characterized by the presence of the "intramedullary canal." [Stroever at col. lines ("The body portion 12 of **each** serrated bone graft section 10 **has** a transverse cavity 13 **(intermedullary canal) extending through body portion 12 between opposite end faces** 16."); emphasis added in bold.] In contrast, the elongate implants of claims 72-80 of the Applicants' invention are "free of a through hole comprising the intramedullary canal of the source bone and extending between said upper surface and said lower surface." For this additional reason, the disclosure in Stroever, wherein the implants are characterized by the presence of the intramedullary canal, would not be anticipatory of new claims 72-80.

The presence of the natural medullary canal in the implants of Stroever supports the Applicants first argument that the implants of Stroever are not elongate, but rather have a uniform length and width (as evidenced by Stroever's use of "diameter") and are "**wide**," *i.e.*, sufficiently wide to accommodate the natural medullary canal of the long bone from which they are derived. For this reason also, Stroever is not anticipatory of claims 59-61, 65-66, and 70-80.

III. Anticipation over U.S. Pat. 6,371,988 (Pafford)

(Claims 59-61, 65-66 and 70-71)

Claims 59-61, 65-66 and 70-71 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,371,988 (Pafford). According to the Patent

Office, "referring to all figures [of Pafford] specifically figures 25 and 28, Pafford teaches a bone implant comprising a substantially planar upper and lower surfaces an anterior end and a posterior end, a first side wall and a second side wall opposite said first side wall, wherein the first and second side walls extend between the planar surfaces, and wherein the second side wall comprises a concave surface (right side of figure 25) and the first wall (left side in figure 25) comprises a convex surface." [Official Action at page 4.] The Patent Office then goes on to state that the implant of figure 25 "is elongate in one direction." [Official Action at page 4.] The Applicants respectfully submit that Pafford's FIG. 25 implant, which is wider than it is long, would not be not anticipatory for the same reason that the wide implant of Stroever is not anticipatory.

Specifically, claim 59 of the Applicants invention is directed to an elongated bone implant, "said first side wall and said second side wall being elongated relative to said anterior end and said posterior end." Thus, the implant of the Applicants claims is elongated in an anterior to posterior direction. In contrast, the implant of figure 25 of Pafford is pear shaped and in the orientation shown by Pafford, it is wider than it is long. For this reason alone, the implant of figure 25 of Pafford is not anticipatory of the elongated implant of the implant of Applicants' claim 59, or any of its dependent claims (claims 61-62 and 65-69) or any of the method claims (claims 70-71) that parallel claim 59.

(Claims 72-80)

Separately, the implants of Pafford all have a through hole. Like Stroever, Pafford discloses that his through hole is the medullary canal of the long bone from which it is derived. [Pafford at col. 6, lines 46-48 ("A preferred load bearing member is obtained from the diaphysis of a long bone having a **medullary canal** which forms a **natural** chamber in the graft.")] In contrast, the elongate implants of the Applicants' invention are "free of a through hole between said upper surface and said lower surface." For this reason also, Pafford is not anticipatory of claim 59 or any of claims 60-61, 65-66 and 70-71.

The presence of the natural medullary canal in the implants of Pafford supports the Applicants first argument (above) that the implants of Pafford are "**wide**" and not elongated, *i.e.*, sufficiently wide to accommodate the natural medullary canal of the

long bone from which they are derived. For this reason also, Pafford is not anticipatory of claims 59-61, 65-66 and 70-80.

IV. 35 U.S.C. § 103(a) Pafford over Kuntz

Claims 59-61, 65-66 and 70-71 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 6,371,988 (Pafford) in view of U.S. Pat. 4,349,921 (Kuntz). In its anticipation argument over Pafford and in the present argument, the Patent Office repeatedly cites to "all figures" in Pafford. [Official Action at page 5.] However, as pointed out previously, FIGS. 9, 10A, 10B, 11A, 11B, 12, 13, 14 15, 21, 22, 23, 34, 37 of Pafford are steel surgical instruments; FIGS. 53, 54, 55, and 59 of Pafford are bar graphs; and FIGS 57-58 of Pafford are mechanical testing devices. Thus, on their face, there is not even a remote argument that any one of the objects in these 20 figures could be anticipatory of an elongated bone implant. Accordingly, the Applicants will only respond to those contentions from the Patent Office for which specific arguments are made.

In a specific argument, the Patent Office contends that in figures 29-32, "Pafford et al teaches a bone implant comprising a substantially planar upper and lower surfaces an anterior end and a posterior end, a first side wall and a second side wall opposite said first side wall, wherein the first and second side walls extend between the planar surfaces, and wherein the second side wall comprises a concave surface and the first wall comprises a convex surface." [Official Action at page 5.] The Patent Office further contends that the preambular term "elongate" fails to "breath life and meaning into the body of the claim." [Official Action at page 5.] The Applicants respectfully disagree. The term "elongate" is a structural term and is not merely a statement of purpose as is the remaining recitation ("for use in spinal fusions") in the preamble. However, to eliminate this argument, the Applicants have amended the body of claim 59 to now recite "said first side wall and said second side wall being elongated relative to said anterior end and said posterior end." Accordingly, the body of claim 59 now includes a recitation of an elongated structure and orientation that is consistent with the preambular recitation of an "elongated" bone implant.

The Patent Office cites to the D-shaped implants of FIGS. 29-32 of Pafford and alleges that the Applicants are claiming half of Pafford's D-shaped implant. The

Patent Office then cites to Kuntz for allegedly teaching that "a spinal implant can be formed in a singular configuration, as shown in figures 1-4, or in two halves, as shown in figures 5-6." [Official Action at page 5.] The Patent Office then concludes that it would have been obvious to one having ordinary skill in the art to have used the teachings of Kuntz forming a spinal implant in two halves with any vertebrae prosthesis including that of Pafford et al because "when a prosthesis for the lumbar area is required, it has been found advantageous to make the prosthesis in two halves. . ." [Official Action at page 5, citing to Kuntz at col. 9, lines 41 et seq.] The Applicants respectfully disagree.

The primary reference, Pafford, discloses implants that are characterized by the presence of the natural medullary canal that is present in the cross-sections of long bone that are used to make the implants of Pafford, including the D-shaped implants of FIGS. 29-32 therein. The secondary reference, Kuntz, discloses **solid** prostheses (implants) that lack a medullary canal. See Kuntz at FIGS. 1-11. Referring to Kuntz at col. 9, lines 41 et seq, which is relied upon by the Patent Office, Kuntz expressly teaches that the referenced 2 halves of the lumbar prosthesis in combination provide the same (solid) prosthesis as FIGS. 1 to 4:

> The prosthesis shown in FIGS. 1 to 4 is intended primarily as a cervical disc prosthesis. When a prosthesis for the lumbar area is required, it has been found advantageous to make the prosthesis in two halves, the division being in a longitudinal (posterior-anterior), vertical plane. Together, the two halves have a width equal to the total size of the space created when bilateral lumbar discectomy is carried out. **Apart from the two-part structure of the lumbar prosthesis, and a difference in overall dimensions, it is the same as the cervical prosthesis described in connection with FIGS. 1 to 4.**
>
> [Kuntz at col. 9, lines 41-52; emphasis added in bold.]

Thus, on its face, Kuntz discloses that but for their two part structure, the lumbar implants are the same as the **solid** implants of FIGS. 1 to 4. Referring to FIGS. 9 and 10 of Kuntz, these halves are shown as **solid** abutting halves that in combination make up a whole implant of FIGS. 1-4. There is no generic teaching in Kuntz that the making of prostheses in halves is applicable to implants having a large hole in the center, *i.e.,* the natural

medullary canal such as in the implants of Pafford. Separately, the Patent Office has already **twice** determined that the applicants D-shaped implants, such as disclosed in Applicants' FIGS 1A-1B and 1C-1D (and as cited in FIGS 29-32 of Pafford) are "patentably distinct species" and have a separate recognition in the art than from the elongated species of e.g. Applicants' 8D-8G. [Exhibit A: Official Action of 09/18/02 is copending sister application USSN 09/722,205 at page 3; also Exhibit B: Official Action of 08/06/03 in copending sister application USSN 09/905,683 at page 2.] Moreover, in both of these applications, the restrictions were made "final." The Patent Office cannot have it both ways. The Applicants' elongated species have already twice been determined by the Patent Office to be "patentably distinct" species from the D-shaped implants with their open hole structure. Hence, Applicants' elongated bone implants cannot be obvious variants of the D-shaped implants of the cited prior art. For this reason, claims 59-61, 65-66 and 70-71 would not be unpatentable under 35 U.S.C. § 103(a) over U.S. Pat. 6,371,988 (Pafford) in view of U.S. Pat. 4,349,921 (Kuntz).

Moreover, the implants of Kuntz are not properly combinable with the implants of Pafford because the implants operate in different ways. The implants of Pafford are made from cross-sections of human cadaver bone and are naturally **porous**. They function by stimulating bone ingrowth and **fusing** the adjacent vertebrae:

> A need has remained for **fusion** spacers which **stimulate bone ingrowth** and **avoid the disadvantages of metal implants** yet provide sufficient strength to support the vertebral column until the **adjacent vertebrae are fused**.
>
> [Pafford at column 3, lines 55-58; emphasis added in bold.]
>
> * * *
>
> One benefit of the spacers of the present invention is that they combine the advantages of bone grafts with the advantages of **metals, without the corresponding disadvantages**. An additional advantage is that the invention provides a stable scaffold for **bone ingrowth** before **fusion** occurs.
>
> [Pafford at column 4, lines 13-17; emphasis added in bold.]

In contrast to Pafford, Kuntz discloses that its implant (prosthesis) is non-porous and does not have tissue ingrowth:

> The tissue does **not grow into** the structure of the prosthesis, **as would be the case if the surface were porous,** but **rather against the surface to encapsulate the prosthesis.**
>
> [Kuntz at col. 6, lines 42-45; emphasis added in bold.]

Kuntz expressly teaches against the use of "porous" materials such as the cortical bone used in Pafford:

> A major **disadvantage** of a **porous material** is that if there is **actual tissue ingrowth** into the prosthesis, **removal could be difficult**. Curetting out the prosthesis would lead to hemorrhage of a very vascular surface area, caused by the tissue ingrowth, with subsequent increased danger of cord compression secondary to hemorrhage.
>
> Besides, any **porous material** allowing tissue ingrowth for stability in a cervical spine **would be dangerous** as the esophagus, which lies anteriorly, could become adhered to the prosthesis with resultant dysphagia or difficulty in swallowing.
>
> There is consequently a **need** for a prosthesis that remains stably in place when implanted but **does not have the difficulties referred to above associated with porous surfaces.**
>
> [Kuntz at col. 2, lines 8-24; emphasis added in bold.]

As a result, Kuntz discloses that its prosthesis (implant) is composed of non-porous synthetic materials, such as "metal" (which Pafford teaches away from using):

> The prosthesis 10 is essentially a spacer and can be **fabricated from** any biologically acceptable material of suitable strength and durability, for example high density polyethylene, polymethylmethacrylate, **stainless steel**, or **chrome cobalt alloys.** The simplest material for fabrication of the prosthesis is a **polymer**, preferably high density polyethylene, and this may include a radiopaque marker so that the position of the prosthesis can be confirmed radiologically.
>
> [Kuntz at col. 7, lines 52-60; emphasis added in bold.]

Thus, the teachings of Pafford and Kuntz are not properly combinable because they teach away from one another and provide opposing solutions to the problem of treating compressed intervertebral discs. *See Monarch Knitting v. Sulzer*, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998) ("A prior art reference may be considered to teach away when 'a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or **would be led in a direction divergent from the path taken by the applicant.**"); emphasis added in bold.

Separately, Kuntz teaches away from the implants of the Applicants' invention which are inherently porous bone allografts that allow for ingrowth and **fusion**. [Specification at page 18, lines 27-28 ("In use, the implant 810 is inserted on either side of lumbar intervertebral spaces to thereby stabilize and assist in **fusion** of adjacent vertebrae."); emphasis added in bold.] For this reason also, claims 59-61, 65-66 and 70-71 would not be unpatentable under 35 U.S.C. § 103(a) over U.S. Pat. 6,371,988 (Pafford) in view of U.S. Pat. 4,349,921 (Kuntz). *See In re Fine*, 5 USPQ2d 1596, 1599 (Fed. Cir. 1988) ("error to find obviousness where references 'diverge from and teach away from the invention at hand'"); *citing Gore v. Garlock*, 220 USPQ 303, 311 (Fed. Cir. 1983). Likewise, claims 72-80, which incorporate these same limitations and which are also free of intramedullary through holes, would not be obvious over Pafford in view of Kuntz.

CONCLUSION

In view of the amendment herein, the rejection of claim 69 under 35 U.S.C. § 112, second paragraph, for indefiniteness has been rendered moot. In view of the amendments herein, the rejection of claims 59-61, 65-66 and 70-71 for anticipation by either Stroever or Pafford has been rendered moot. In view of the arguments herein, the rejection of claims 59-61, 65-66 and 70-71 under 35 U.S.C. § 103(a) for allegedly being unpatentable over Pafford in view of Kuntz has been rebutted. Claims 59-61, 65-66 and 70-71 are in condition for allowance. Their allowance is respectfully requested.

Respectfully submitted,

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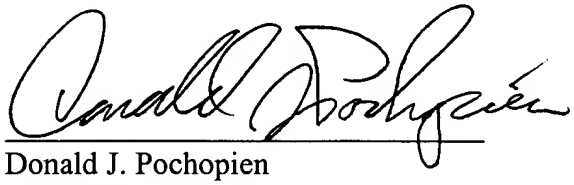
By: 

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